

## **CLAIMS**

What is claimed is:

1. A method of preparing an immunologically inert graft material comprising the steps of:
  - procuring body tissues from one of an autologous, heterologous or allogenic source;
  - soaking the body tissues in a bleach solution;
  - rinsing the body tissues in water to remove bleach solution from the tissues;
  - washing the body tissues in a detergent solution;
  - rinsing the body tissue to remove the detergent solution.
  - trimming the body tissue to a desired physical form;
  - soaking the body tissue in an iodophor solution;
  - rinsing the body tissue to remove the iodophor solution;
  - soaking the body tissue in a hypertonic solution;
  - rinsing the body tissue to remove the hypertonic solution therefrom;
  - agitating the body tissue in a caustic solution;

15 rinsing the body tissue in water under agitation to remove the caustic solution  
16 therefrom;  
17 treating the body tissue with a peroxide solution under agitation;  
18 rinsing the body tissue in sterile water; and  
19 conserving the body tissues in a sterile environment until needed.

1 2. The method of preparing a graft material of claim 1 wherein the hypertonic  
2 solution is a saline solution.

1 3. The method of preparing a graft material of claim 1 wherein the step of soaking  
2 the body tissue in a hypertonic solution further comprises the steps of:  
3 soaking the body tissue in a series of increasingly hypertonic solutions and  
4 rinsing the body tissue after each soaking in a hypotonic solution to remove the  
5 hypertonic solution therefrom.

1 4. The method of preparing a graft material of claim 1 wherein the caustic solution  
2 comprises one of sodium hydroxide, potassium hydroxide, ammonium hydroxide,  
3 calcium hydroxide, sodium dodecylsulfate, urea, phenol, and formic acid.

1 5. The method of preparing a graft material of claim 1 wherein the caustic solution  
2 comprises a sodium hydroxide solution having a concentration of between .75 N  
3 and 1.25N.

1 6. The method of preparing a graft of material of claim 3 wherein the series of  
2 hypertonic solutions comprise 2%, 4%, 6%, 8%, 10% and 12% saline solutions.

1 7. The method of preparing a graft material of claim 1 wherein the body tissue is  
2 immersed in hydrogen peroxide in a reaction chamber comprising:  
3 a receptacle portion into which hydrogen peroxide and the body tissue are  
4 placed;  
5 an agitation that is supported upon an axle with in the receptacle and which  
6 rotates so as to agitate the hydrogen peroxide and body tissue; and  
7 a perforated cover placed over the receptacle so as to maintain the body tissue  
8 below the surface of the hydrogen peroxide.

1 8. An immunologically inert graft material produced by the method of claim 1.

1 9. A method of preparing an immunologically inert graft material comprising the  
2 steps of:

3 washing the body tissue in a detergent solution;

4 treating the body tissue with one or more anti-microbial and anti-viral solutions;

5 soaking the body tissue in a hypertonic solution;

6 soaking the body tissue in a solution comprising a caustic reagent;

7 treating the body tissue with a hydrogen peroxide solution; and

8 conserving the body tissue in a sterile environment.

1 10. A method of preparing an implantable graft material by removing cellular  
2 components from a preexisting extra cellular matrix comprising the steps of:

3 freezing and subsequently thawing an untreated portion of the extracellular  
4 matrix in a bleach solution;

5 washing the extracellular matrix in a detergent solution;

6 lysing cellular components present in the extracellular matrix by soaking the  
7 extracellular matrix in a hypertonic solution;

8           soaking the extracellular matrix in a solution of sodium hydroxide; and,  
9           soaking the extracellular matrix in a solution of hydrogen peroxide.

1   11.   The method of preparing an implantable graft material of claim 10 further  
2       comprising the step of treating the extracellular matrix with an antibacterial  
3       agent.

5  
1   12.   The method of preparing an implantable graft material of claim 10 further  
2       comprising the step of soaking the extra cellular material in an iodophor solution.

1   13.   The method of preparing an implantable graft material of claim 10 further  
2       comprising the step of treating the extracellular matrix with an antibiotic solution.

1   14.   The method of preparing an implantable graft material of claim 10 further  
2       comprising the step of treating the extracellular matrix with an antibiotic solution  
3       comprising kanamycin.

1   15.   The method of preparing a graft material of claim 1 wherein the body tissue is  
2       additionally treated with a bactericidal agent.

1 16. The method of preparing a graft material of claim 1 wherein the hydrogen  
2 peroxide solution may be replaced by one of peracetic acid, perbenzoic acid,  
3 benzoyl peroxide, sodium peroxide, and potassium permanganate.

1 17. The method of preparing an immunologically inert graft material of claim 9  
2 wherein the anti-bacterial solution comprises one of an iodophor and a bleach.

1 18. The method of preparing an immunologically inert graft material of claim 9  
2 wherein the anti-bacterial solution comprises one of povidone-iodine, sodium  
3 hypochlorite, and calcium hypochlorite.

1 19. The method of preparing an immunologically inert graft material of claim 10  
2 wherein one of potassium hydroxide, ammonium hydroxide, calcium hydroxide,  
3 sodium dodecylsulfate, urea, phenol, and formic acid may be substituted for  
4 sodium hydroxide.

1 20. The method of preparing an immunologically inert graft material of claim 9  
2 wherein one of peracetic acid benzoyl peroxide, sodium peroxide, potassium  
3 permanganate may be substituted for hydrogen peroxide.

1 21. The method of preparing an immunologically inert graft material of claim 9  
2 wherein the bleach solution may comprise one of sodium hypochlorite and  
3 calcium hypochlorite.

1 22. The method of preparing an immunologically inert graft material of claim 10  
2 wherein an iodophor may be substituted for the bleach solution.

1 23. The method of preparing an immunologically inert graft material of claim 22  
2 wherein the iodophor comprises povidone-iodine.

1 24. The method of preparing an immunologically inert graft material of claim 1  
2 further comprising the steps of initially freezing the body tissues in a first bleach  
3 solution for a predetermined time and at a predetermined temperature and then  
4 thawing the body tissues in a second bleach solution.

1 25. The method of preparing an immunologically inert graft material of claim 9  
2 further comprising the step of freezing, and subsequently thawing a preselected  
3 quantity of body tissue in a bleach solution.

1 26. A method of preparing an immunologically inert graft material from a body tissue  
2 having cellular material disposed within an extracellular matrix comprising the  
3 steps of:

4 lysing the cellular material disposed within the extracellular matrix by cycling the  
5 relative osmotic pressure the cellular material is exposed to by  
6 alternately exposing the body tissue to a hypertonic solution and a  
7 hypotonic solution;

8 deactivating antigens present in the body tissue by exposing the body tissue to  
9 at least one of a bleach solution, sodium hydroxide, and an iodophor  
10 solution; and,  
11 stabilizing the body tissue by soaking it in an isotonic solution.

1 27. The method of preparing an immunologically inert graft material from a body  
2 tissue of claim 26 further comprising the step of exposing the body tissue to a  
3 sodium hydroxide solution.

1 28. The method of preparing an immunologically inert graft material from a body  
2 tissue of claim 26 further comprising the step of exposing the body tissue to a  
3 hydrogen peroxide solution.

1 29. The method of preparing an immunologically inert graft material from a body  
2 tissue of claim 26 further comprising the step of exposing the body tissue to an  
3 antibiotic solution.

1 30. The method of preparing an immunologically inert graft material from a body  
2 tissue of claim 26 further comprising the step of initially freezing the body tissue  
3 in a bleach solution.

1 31. The method of preparing an immunologically inert graft material from a body  
2 tissue of claim 26 wherein the hypertonic and hypotonic solutions are ionic and  
3 non-ionic aqueous solutions, respectively.



1 32. The method of preparing an immunologically inert graft material from a body  
2 tissue of claim 26 wherein the hypertonic solution is an aqueous saline solution  
3 and the hypotonic solution is water.

1 33. The method of preparing an immunologically inert graft material from a body  
2 tissue of claim 32 wherein the body tissue is exposed to an increasingly  
3 hypertonic series of saline solutions.

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